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M. Russell

C 1

dti
the department for Enterprise

**PATENTS ACT 19**

PATENTS FORM NO. 1/77 (Revised 1982)

(Rules 16, 19)

The Comptroller
The Patent Office

22 MAR 1989

22 MAR 1989

## REQUEST FOR GRANT OF A PATENT

8906570.0

**THE GRANT OF A PATENT IS REQUESTED BY THE UNDERSIGNED ON THE BASIS OF THE PRESENT APPLICATION**

I Applicant's or Agent's reference *(Please insert if available)* Agent's ref. 63850/LPS

II Title of invention ARTIFICIAL AIRWAY DEVICE

III Applicant or Applicants *(See note 2)*

Name (First or only applicant) Archibald Ian Jeremy Brain 9767L2002

Country England State ADP Code No

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~~Name (of second applicant, if more than one)~~

~~Country~~ ~~State~~

~~Address~~

IV Inventor (see note 3)

(a) The applicant(s) is/~~are~~ the sole/~~joint~~ inventor(s)

~~or~~

~~(b) A statement on Patents Form No 7/77 is/will be furnished~~

V Name of Agent (if any) *(See note 4)* Page White & Farrer 125500/ ADP CODE NO

VI Address for Service *(See note 5)*

5 Plough Place, New Fetter Lane, London EC4A 1HY

VII Declaration of Priority *(See note 6)*

| Country | Filing date | File number |
|---|---|---|
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VIII The Application claims an earlier date under Section 8(3), 12(6), 15(4), or 37(4) *(See note 7)*

Earlier application or patent number and filing date

IX Check List *(To be filled in by applicant or agent)*

| A | The application contains the following number of sheet(s) | | B | The application as filed is accompanied by:- | |
|---|---|---|---|---|---|
| 1 | Request | 1 Sheet(s) | 1 | Priority document | No |
| 2 | Description | 9 Sheet(s) | | Translation of priority document | No |
| 3 | Claim(s) | 2 Sheet(s) | 3 | Request for Search | Yes |
| 4 | Drawing(s) | 3 Sheet(s) | 4 | Statement of Inventorship and Right to Grant | No |
| 5 | Abstract | 1 Sheet(s) | | | |

X It is suggested that Figure No. 4 of the drawings (if any) should accompany the abstract when published.

XI Signature *(See note 8)* Page White & Farrer

Page White & Farrer (Agents for the Applicant)

NOTES:

1. This form, when completed, should be brought or sent to the Patent Office together with the prescribed fee and two copies of the description of the invention, and of any drawings.

2. Enter the name and address of each applicant. Names of individuals should be indicated in full and the surname or family name should be underlined. The names of all partners in a firm must be given in full. Bodies corporate should be designated by their corporate name and the country of incorporation and, where appropriate, the state of incorporation within that country should be entered where provided. Full corporate details, eg a "corporation organised and existing under the laws of the State of Delaware, United States of America", trading styles, eg "trading as xyz company", nationality, and former names, eg "formerly (known as) ABC Ltd" are *not* required and should *not* be given. Also enter applicant(s) ADP Code No.(if known).

3. Where the applicant or applicants is/are the sole inventor or the joint inventors, the declaration (a) to that effect at IV should be completed, and the alternative statement (b) deleted. If, however, this is not the case the declaration (a) should be struck out and a statement will then be required to be filed upon Patent Form No 7/77.

4. If the applicant has appointed an agent to act on his behalf, the agent's name and the address of his place of business should be indicated in the spaces available at V and VI. Also insert agent's ADP Code No. (if known) in the box provided.

5. An address for service in the United Kingdom to which all documents may be sent must be stated at VI. It is recommended that a telephone number be provided if an agent is not appointed.

6. The declaration of priority at VII should state the date of the previous filing and the country in which it was made and indicate the file number, if available.

7. When an application is made by virtue of section 8(3), 12(6), 15(4) the appropriate section should be identified at VIII and the number of the earlier application or any patent granted thereon identified.

8. Attention is directed to rules 90 and 106 of the Patent Rules 1982.

9. Attention of applicants is drawn to the desirability of avoiding publication of inventions relating to any article, material or device intended or adapted for use in war (Official Secrets Acts, 1911 and 1920). In addition after an application for a patent has been filed at the Patent Office the comptroller will consider whether publication or communication of the invention should be prohibited or restricted under section 22 of the Act and will inform the applicant if such prohibition is necessary.

10. Applicants resident in the United Kingdom are also reminded that, under the provisions of section 23 applications may not be filed abroad without written permission or unless an application has been filed not less than six weeks previously in the United Kingdom for a patent for the same invention and no direction prohibiting publication or communication has been given or any such direction has been received.

# ARTIFICIAL AIRWAY DEVICE

This invention relates to artificial airway devices to facilitate lung ventilation in unconscious patients, and more specifically to such devices designed for placing in the oropharynx of the patient in order to prevent airway obstruction and to permit either spontaneous or controlled ventilation.

To maintain the airway of an unconscious patient, and to achieve the objectives mentioned above, it is normal practice in general anaesthesia to use an endotracheal tube, which is a flexible tube of rubber or plastics, usually with an inflatable cuff around the distal end. Alternatively, an oro- or naso-pharyngeal airway may be used, which is a flexible tube extending from the mouth or nose into the pharynx but not into the larynx, and which is used in conjunction with a face mask, unlike the endotracheal tube. While preventing obstruction of the airway by the tongue, the oro- or naso-pharyngeal airway cannot conveniently be used for controlled ventilation and does not prevent inhalation of extraneous matter.

The endotracheal tube is introduced through the larynx into the trachea or windpipe, whereupon the cuff is inflated through a small auxiliary tube to seal against the wall of the trachea. Introduction of the endotracheal tube is a skilled operation normally requiring use of a laryngoscope to guide the tube through the larynx, past the vocal cords and into the trachea. There is a risk that the tube or the laryngoscope may cause damage to soft tissues or to the sensitive structures of the larynx. It is not always possible to see the larynx, making intubation difficult or impossible in some patients. There can be a risk of accidental intubation of

the oesophagus or of the right or left main bronchus. Placing of the tube in the trachea effectively narrows the interior passage or lumen of the trachea and provides a potential source of damage through infection or pressure while preventing normal upward flow of mucus from the trachea and rendering effective coughing impossible.

In my British Patent Specification No. 2111394B, I have described and claimed an artificial airway device comprising a curved or flexible tube and a mask portion carried at one end of the tube, the mask portion having a flexible annular peripheral formation which may be inflatable and which surrounds a hollow interior space or lumen of the mask portion, said annular peripheral formation of the mask portion being pre-formed with a roughly elliptical shape such as to be capable of conforming to, and of fitting readily within, the actual and potential space behind the larynx so as to form a seal around the circumference of the laryngeal inlet without the device penetrating into the interior of the larynx, the tube opening into the lumen of the mask portion to provide the airway with the axis of the tube substantially aligned with the length of the roughly elliptical annular peripheral formation of the mask portion. The device thus constitutes a laryngeal mask. In practice, the annular peripheral formation has been made as an inflatable tube, e.g. of a silicone rubber.

This device has proved successful in use. Insertion of the device has been found to be easy and convenient in the majority of patients. A laryngoscope is not usually required. The mask does not enter the larynx or trachea so the risk of damage to these structures is avoided and the tracheal lumen is not narrowed as it is by insertion of an endotracheal tube. The risk of accidental entry

into the oesophagus or one of the main bronchi is also avoided. Once in place the laryngeal mask generally permits the lungs to be ventilated by positive pressure. Alternatively the patient may be permitted to breathe spontaneously.

To avoid the risk that the epiglottis could obstruct the airway by falling inwards into the lumen of the mask and blocking the opening of the tube therein, which could happen, for example, with small displacements of the mask which may occur during surgery or manipulation of the patient on the operating table, I have described in my Patent Application No. 8713173 (Publication No 2205499A) an artificial airway device of the kind described above wherein the airway tube opens into the lumen of the mask through an aperture which is provided with means, such as flexible cross-bars, to prevent it from being obstructed by the epiglottis while permitting passage of a second smaller tube, when required. Such a tube may be, for example, an endotracheal or endobronchial tube or a suction catheter, or an inspection tube such as a fibre-optic broncho- or laryngoscope.

The seal around the circumference of the laryngeal inlet which has been achieved, using an inflatable annular peripheral formation of the mask, has been found fully adequate in most circumstances. There are occasions, however, when an improved seal could be advantageous, e.g. to reduce the possibility that air might be allowed into the stomach when the patient's lungs are being ventilated under positive pressure, or to reduce the possibility that food regurgitated from the stomach might enter the lumen of the mask and the larynx.

According to the present invention, there is provided an artificial airway device to facilitate lung ventilation in an unconscious patient, comprising an airway tube and a mask carried at one end of the airway tube, the mask having a flexible annular peripheral formation of roughly elliptical shape capable of conforming to, and of readily fitting within, the actual and potential space behind the larynx so as to form a seal around the circumference of the laryngeal inlet without the device penetrating into the interior of the larynx, the annular peripheral formation surrounding a hollow interior space or lumen of the mask into which the airway tube opens, wherein the annular peripheral formation carries a soft, flexible, upstanding collar surrounding the lumen of the mask so as to improve the sealing contact with the tissues around the circumference of the laryngeal inlet.

Preferably the collar is formed of a flexible sheet material, and is adhered at its base to the adjacent surface of the annular peripheral formation.

The flexible annular peripheral formation is inflatable.

In a preferred embodiment of the invention, the inflatable peripheral formation is formed as a tubular ring and the collar is curved, as seen in cross-section, in the reverse sense to the walls of the tubular ring, so that the base of the collar is parallel to the adjacent surface of the ring and its free end extends away from the lumen of the mask.

The tube and collar may be made of a silicone rubber sheet material of similar thickness to one another.

A drainage tube of smaller diameter than the airway tube may be accommodated in the airway tube, with one end opening into the lumen of the mask and the other end capable of being positioned below the patient for extracting fluid from the lumen of the mask by syphonic action, or of being connected to suction apparatus for extracting such fluid by suction.

Alternatively or in addition, a drainage tube may have a forked end adhered to the outside of a part of the periphery of the collar, the other end of the drainage tube being capable of being positioned below the patient for extracting fluid from the area around the exterior of the mask by syphonic action, or of being connected to suction apparatus for extracting such fluid by suction.

Specific embodiments of the invention will now be described in more detail by way of example and with reference to the accompanying drawings, in which:-

Figure 1 is a side view of an artificial airway device in the form of a laryngeal mask,
Figure 2 is a plan view of the device with the periphery of the mask portion inflated,
Figure 3 is a section on the line III-III of Figure 2,
Figure 4 shows diagrammatically the device in position for use in a patient.
Figure 5 is a side view of a modified form of laryngeal mask, and
Figure 6 is a plan view of the device of Figure 5.

The laryngeal mask illustrated in Figures 1 to 4 of the drawings comprises a flexible airway tube 10 of silicone rubber material, similar to that used for some endotracheal tubes, and a mask 12 of flexible silicone

rubber sheet material, having an inflatable tubular ring 14 of the same silicone rubber material forming its periphery and a web 16 which closes off the rear of the interior or lumen 18 of the mask and is formed with an aperture 19. The distal end 20 of the airway tube 10 is secured, as by welding, in one end of a short piece 22 of thick-walled silicone rubber tubing whose other end is moulded to fit against the outer edge of the web 16 and around the aperture 19, so as to form a semi-rigid backpiece for the mask, which backpiece carries the airway tube 10 at an angle of substantially $30^{o}$ to the plane of the ring 14. The airway tube 10 thus opens into the interior or lumen 18 of the mask 12 through the piece 22 and the aperture 19. The peripheral ring 14 is of roughly elliptical shape as seen in plan (Figure 2) though its distal end 15 may be slightly elongated to conform with the triangular shape of the base of the hypopharynx where it becomes continuous with the upper end of the oesophagus. The airway tube 10 lies in substantially the same plane as the major axis of the peripheral ring 14 and at substantially $30^{o}$ to the plane of the ring 14. The ring 14 is formed with a port 24 into which is sealed one end of a flexible silicone rubber tube 26 of much smaller diameter. The other end of tube 26 is provided with an inflation indicator 28, and can be connected to a small pump (not shown) such as a disposable 20 ml medical syringe for inflation of the ring 14. Alternatively the tube 26 may be permanently connected through a valve to a collapsible bulb whose capacity is equal to the optimal inflated capacity of the ring 14.

The aperture 19 through which the airway tube 10 opens into the lumen 18 of the mask 12 is provided with two flexible cross-bars 21 extending across the aperture 19 substantially parallel with the major axis of the

peripheral ring 14, so as to leave the middle of the aperture clear for passage of an inspection or other tube. The bars 21 effectively prevent the epiglottis from falling into the aperture 19 and obstructing the airway.

In accordance with the present invention, a soft flexible upstanding collar 27, surrounding the lumen 18 of the mask, is formed of flexible sheet material, e.g. of a silicone rubber sheet material of similar thickness to that of the tubular ring 14. The collar 27 is adhered at its base to the adjacent surface 29 of the ring 14, and is curved, as seen in cross-section in Figure 3, in the reverse sense to the walls of the ring 14, so that the base of the collar 27 is parallel to the adjacent surface 29 of the ring 14 and its free end extends away from the lumen 18 of the mask. The collar 27 is designed to offer a low profile on deflation of the ring 14, to assist insertion and removal of the laryngeal mask. When the laryngeal mask is in place and the ring 14 is inflated, the collar 27 is found to improve the effectiveness of the seal between the mask and the tissues of the laryngeal inlet by about 30% on average, and thereby to reduce the risk of allowing air under positive pressure into the stomach and to improve the exclusion of any regurgitated food from the interior of the mask and hence from the larynx.

In some circumstances it can be advantageous to provide a small diameter drainage tube, as shown at 40 in Figures 1 to 3, accommodated in the airway tube 10, with one end 41 opening into the lumen 18 of the mask and the other end of sufficient length to be capable of being positioned below the patient for extracting fluid from the lumen of the mask by syphonic action, or of being connected to suction apparatus for extracting fluid by suction.

Different sizes of mask are needed for different sizes of patient. In use, the ring 14 is first fully deflated and the device is inserted through the patient's mouth 30 and down through the throat 31 past the epiglottis 32 until the mask 12 comes to rest in the position shown in Figure 4, with the distal end 15 of the ring 14 in the base 33 of the throat, lying against the upper end of the normally closed oesophagus 34, which the mask cannot easily enter provided that the correct size has been chosen. The ring 14 is then inflated as shown to increase the sealing pressure around the inlet 36 to the larynx 38. The collar 27 is flattened between the ring 14 and the inlet 36 to improve the seal. The patient's airway is thus secure and unobstructed and the laryngeal mask can be connected directly to conventional anaesthetic circuit hosing for either positive pressure or spontaneous breathing. As can be seen from Fig. 4, the airway tube 10 opens into the lumen of the mask 12 at the appropriate angle (substantially $30^{\circ}$) to enable an inspection or other tube (not shown) passed through the airway tube 10 and the mask 12 to emerge at the correct angle for intubation of the larynx 38.

As shown in Figures 5 and 6, a small diameter drainage tube 42 may be provided, with a forked end 43 adhered to the outside of the collar 27 around a part of its periphery, so as to be capable of extracting fluid or regurgitated food from the area around the exterior of the mask. Again the end of the drainage tube 42 should be capable of being positioned below the patent to allow extraction of fluid by syphonic action, or of being connected to suction apparatus for extraction of fluid by suction.

The embodiment described above may be used as a disposable instrument or as a re-usable one.

Although only a single collar 27 has been described above and shown in the accompanying drawings, it would be possible for the ring 14 to carry two or more such collars, disposed parallel to and one within the other.

The tube and mask portion could be made of other sterilisable materials, such as plastics. The materials may be more rigid than the inflatable silicone rubber materials described above. With some materials it may not be necessary that the peripheral ring should be inflatable. For example, the ring 14 may consist of a foam material within an air-tight covering, from which the air is evacuated to facilitate insertion of the mask. In any case the mask 12 will be shaped as described above to conform to and fit readily into the actual and potential space behind the larynx and to seal around the laryngeal inlet. The reference to actual and potential space will be understood to refer to the space normally available and that which can become available on flexure of the surrounding structures.

Claims

1. An artificial airway device to facilitate lung ventilation in an unconscious patient, comprising an airway tube and a mask carried at one end of the airway tube, the mask having a flexible annular peripheral formation of roughly elliptical shape capable of conforming to, and of readily fitting within, the actual and potential space behind the larynx so as to form a seal around the circumference of the laryngeal inlet without the device penetrating into the interior of the larynx, the annular peripheral formation surrounding a hollow interior space or lumen of the mask into which the airway tube opens, wherein the annular peripheral formation carries a soft, flexible, upstanding collar surrounding the lumen of the mask so as to improve the sealing contact with the tissues around the circumference of the laryngeal inlet.

2. An artificial airway device according to claim 1 wherein the collar is formed of a flexible sheet material, and is adhered at its base to the adjacent surface of the annular peripheral formation.

3. An artificial airway device according to claim 1, wherein the flexible annular peripheral formation is inflatable.

4. An artificial airway device according to claim 3 wherein the inflatable peripheral formation is formed as a tubular ring and the collar is curved, as seen in cross-section, in the reverse sense to the walls of the tubular ring, so that the base of the collar is parallel to the adjacent surface of the ring and its free end extends away from the lumen of the mask.

5. An artificial airway device according to claim 4 wherein the tubular ring and collar are made of a silicone rubber sheet material of similar thickness to one another.

6. An artificial airway device according to any one of the preceding claims, wherein two or more of said soft, flexible upstanding collars are carried by the annular peripheral formation and surround the lumen of the mask.

7. An artificial airway device according to any one of the preceding claims, wherein a drainage tube of smaller diameter than the airway tube is accommodated in the airway tube, with one end opening into the lumen of the mask and the other end capable of being positioned below the patient for extracting fluid from the lumen of the mask by syphonic action, or of being connected to suction apparatus for extracting such fluid by suction.

8. An artificial airway device according to any one of the preceding claims, wherein a drainage tube has a forked end adhered to the outside of a part of the periphery of the collar, the other end of the drainage tube being capable of being positioned below the patient for extracting fluid from the area around the exterior of the mask by syphonic action, or of being connected to suction apparatus for extracting such fluid by suction.

9. An artificial airway device for facilitating lung ventilation in an unconscious patient, substantially as herein described and as illustrated in Figures 1 to 4 or of Figures 5 and 6 of the accompanying drawings.

ABSTRACT

ARTIFICIAL AIRWAY DEVICE

An artificial airway device, for use in place of an endotracheal tube to facilitate lung ventilation in an unconscious patient, is in the form of a laryngeal mask comprising an airway tube (10) opening into the interior space or lumen of a mask portion (12) whose periphery (14), which may be inflatable, is adapted to seal around the inlet (36) to the larynx (38), thus securing the patient's airway and permitting spontaneous or controlled ventilation. A soft, flexible upstanding collar (27) is carried by the periphery (14) of the mask, so as to surround the lumen of the mask and improve the sealing contact with the tissues around the circumference of the laryngeal inlet (36).

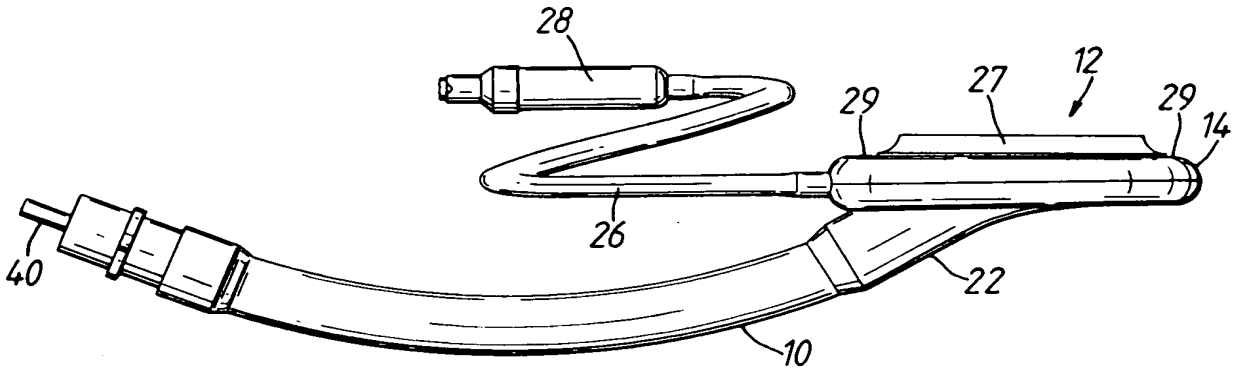


Fig. 1.

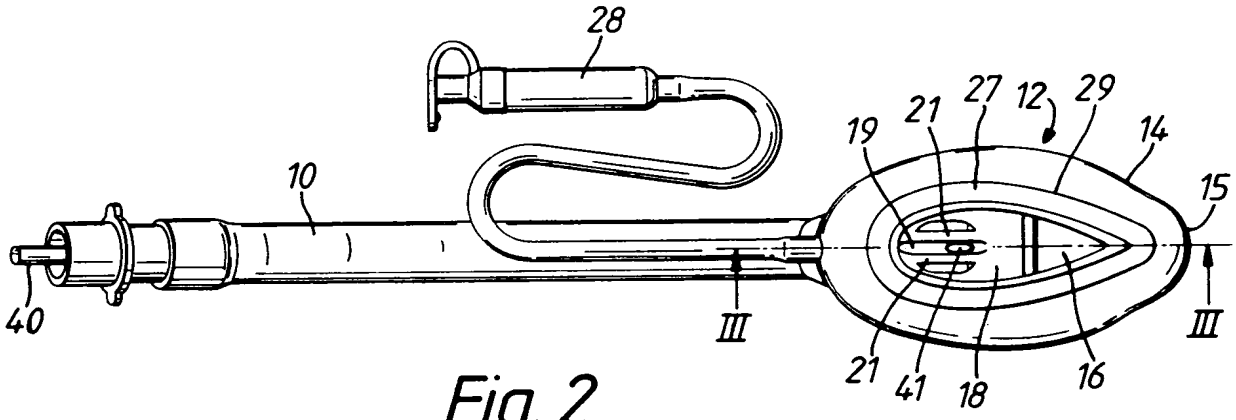


Fig. 2.

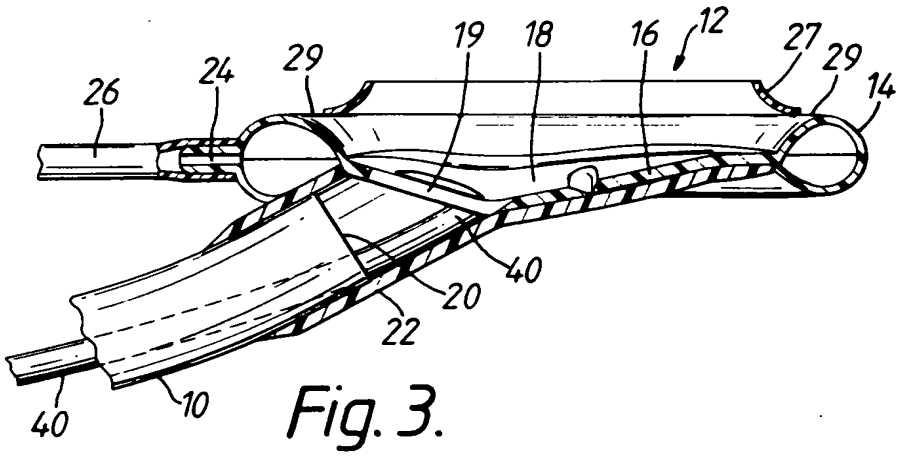


Fig. 3.

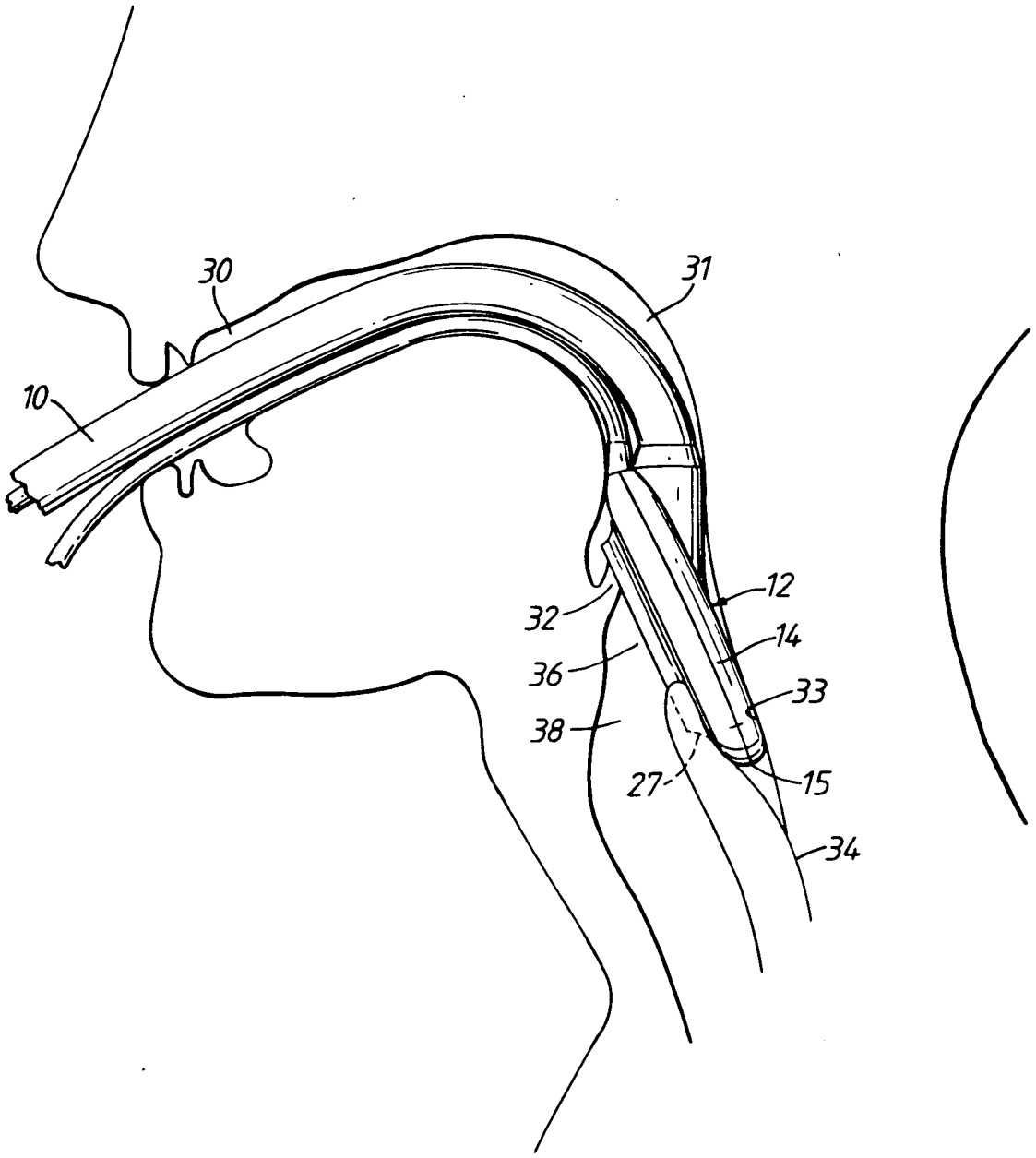


Fig. 4.

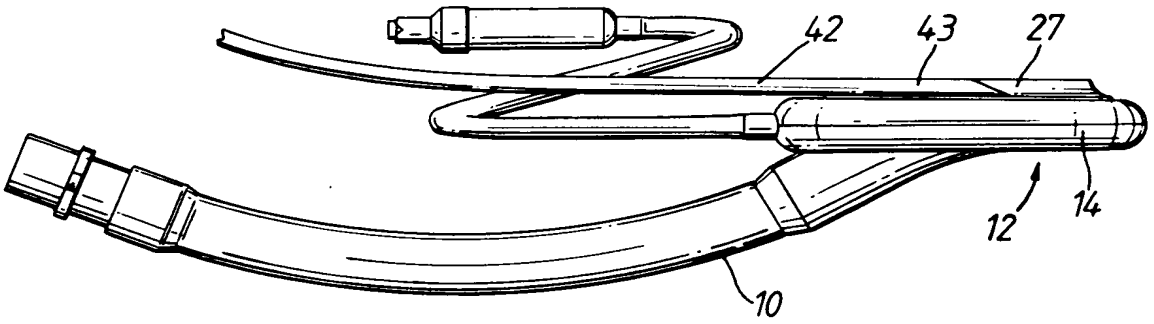


Fig. 5.

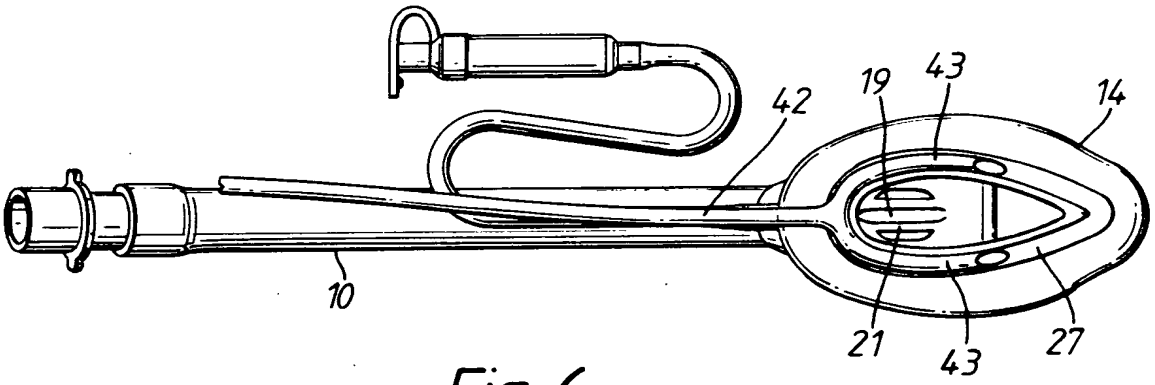


Fig. 6.